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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,665	09/25/2001	Peter Becker	48498-0120(2)	6282
23370	7590	05/19/2004	EXAMINER YANG, NELSON C	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309			ART UNIT 1641	PAPER NUMBER

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,665	BECKER ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-124 is/are pending in the application.
- 4a) Of the above claim(s) 59-124 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/07/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 28-58 is acknowledged. The traversal is on the ground(s) that the groups I-IX, which were restricted on the basis of different types of assays and beads, represent a single inventive concept, and that the invention is completely independent of specific methods for detecting analytes. This is found persuasive, and therefore the restriction of groups I-IX is withdrawn.
2. With respect to groups X-XXVII, applicant has not traversed the restriction thereof, and since the support recited in claims 58-91 would still read upon the prior art recited in the prior office action, therefore the requirement for group is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 28-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. With respect to claim 28, it is not entirely clear when the step of applying a material layer to the substrate occurs. Specifically, the order of the steps would suggest that this limitation occurs after contacting the sample to the detection fields on the substrate. However, the way the claim is written – “and wherein, a material layer, which aids in the evaluation of the detection

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fields, is applied to the surface of the substrate” would suggest that this limitation occurs prior to contacting the sample with the detection fields.

6. With respect to claim 29, it is unclear what would constitute “radial separation”, rendering the claim indefinite.

7. With respect to claim 36, applicant recites the limitation that the material layer “is arranged with separation from the substrate”. However, in claim 28, applicant recites the step where the material layer is applied to the surface of the substrate, rendering it unclear what is meant by the limitation recited in claim 36. Currently this limitation is interpreted as the material layer is distinct from the substrate.

8. Claim 43 recites the limitation “the reflecting layer” in the first line. There is insufficient antecedent basis for this limitation in the claim. This is also applicable to the limitation “the reflecting layer” in claim 44.

9. The remaining claims are indefinite due to their dependence on indefinite claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 28-47, 50-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Virtanen [US 6,342,349].

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With respect to claims 28-30, Virtanen teaches a method comprising the steps of contacting an assay device with a sample, and then detecting, using an optical disk reader, analyte specific signals (column 6, lines 7-10). The assay device can comprise both concentric patterns or spiral patterns along which cleavable signal elements are located, such that assay of multiple samples is possible (figs 11A-G, 12, 39, 44, column 45, lines 1-30, column 46, lines 1-9, 19-36). And the substrate of the assay device is provided with a derivatized surface to which is attached cleavable spacer molecules and metal microspheres (column 16, lines 1-15). Virtanen further teach that the assay device may be comprised of two disks of optically clear polycarbonate, with the top disk having a circular gold mirror evaporated near the center (column 54, lines 25-44).

12. With respect to claims 31-34, Virtanen teaches the use of an address line from which the location of cleavable spacers can be measured, as well as interpretive software on central tracks (column 46, lines 19-36, figs. 11A-G).

13. With respect to claim 35, 36, Virtanen teaches an embodiment in which a polycarbonate substrate has impressed upon it a continuous spiral groove as a reference guide, with an organic dye used to form a data layer, which is sandwiched between the substrate and a metalized reflective layer (column 39, lines 1-20). Opaque dye-containing particles may be used as a light-responsive signal moiety, preventing reflection of laser light from the metallic layer of the disk substrate (column 39, lines 40-49).

14. With respect to claim 37, the analytes can be detected by an immunoassay (column 17, lines 34-67).

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15. With respect to claims 38, the method taught by Virtanen can involve optical evaluation using laser reflectance-based detectors (column 15, lines 60-65).

16. With respect to claims 39, 40, the substrate comprises polycarbonate (column 15, lines 65-67).

17. With respect to claims 41-42, 45, 46, 50, the substrate is provided with a derivatized surface to which is attached cleavable spacer molecules and metal microspheres (column 16, lines 1-15). Virtanen further teach that the assay device may be comprised of two disks of optically clear polycarbonate, with the top disk having a circular gold mirror evaporated near the center (column 54, lines 25-44). Virtanen also teach an embodiment in which an organic dye layer is sandwiched between a polycarbonate substrate and a metalized reflective layer, in which case the absence of reflected light from an addressed location indicates capture of analyte (column 38, lines 55-64).

18. With respect to claims 43-44, Virtanen teaches the use of an assay device comprising aluminum or some other metal coated with plastics (column 60, lines 54-61). Currently the reflecting layer is assumed to be part of the substrate.

19. With respect to claim 47, Virtanen teaches that spatial distribution of cleavable reflective signal elements may be designed to facilitate the quantitation of analyte concentration, such that the concentration of analytes may be determined. In one geometry, a single sample is channeled in parallel into four distinct sectors of the assay device, in which if the density or affinity of the biobits differs, a large dynamic range of concentration may be determined by detecting the position in each sector of the positive biobit most distal from the sample application device (column 46, line 45 – column 47, lines 16).

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20. With respect to claims 51-55, Virtanen teaches that magnetic spheres can be used and oriented by treating the disk with a magnetic field of sufficient strength. The magnetic material can be added after hybridization of the sample to provide the signal generating means (column 41, lines 38-46).

21. With respect to claims 56-58, Virtanen teaches the application of an optically clear plastic coating (column 25 lines 38-47).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claims 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen [US 6,342,349] in view of Kitajima et al [US 4,356,149].

Virtanen teaches the use of an optically clear plastic coating as discussed above. Virtanen do not teach the application of the coating after contacting the sample with the detection fields and before application of the material layer.

Kitajima et al, however, do teach that the use of an adhesion layer for the purpose of firmly bonding an aqueous liquid sample layer or firmly attaching two separate layers (column 2, lines 1-34, column 6, lines 24-37). Therefore, it would have been obvious to have an adhesion layer, as suggested by Kitajima et al, in the method of Virtanen, in order to firmly attach two separate layers.

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Conclusion

24. No claims are allowed.

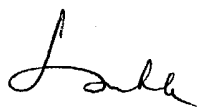
25. The following references are also cited as art of interest: Virtanen [US 6,030,581], Virtanen [US 6,274,373], Zaffaroni et al [US 6,121,048], and Nolte et al [US 6,685,885], teach methods of using bio and optical disc systems for performing assays.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641


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07/02/04